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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/089,120	03/22/2002	Yutaka Tokiwa	11283-018001	9082
26211	7590	03/18/2004		
FISH & RICHARDSON P.C. 45 ROCKEFELLER PLAZA, SUITE 2800 NEW YORK, NY 10111			EXAMINER AFREMOVA, VERA	
			ART UNIT 1651	PAPER NUMBER

DATE MAILED: 03/18/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/089,120	TOKIWA, YUTAKA	
	Examiner	Art Unit	
	Vera Afremova	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 December 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 1 and 4-19 is/are pending in the application.
- 4a) Of the above claim(s) 4-18 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) 1 and 19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of claims

Claim 1 as amended and new claim 19 {12/17/2003} are pending and under examination.

Claims 2 and 3 are canceled by applicant (12/17/2003).

Claims 4-18 have been withdrawn as directed to non-elected invention. Election was made without traverse {5/30/2003}. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Claim Rejections - 35 USC § 102

Claim rejections under 35 USC 102 (b or e) as being anticipated by US 5,925,556 or US 6,066,492 have been withdrawn because the cited patents they do not disclose particular species within the genus of *Saccharothrix* that are capable of degrading polylactide resins.

However, the cited patents US 5,925,556 and US 6,066,492 disclose a method for degrading polylactide resins by a generic actinomycete microorganism belonging to the actinomycete genus *Saccharothrix*.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1 as amended and new claim 19 remains/is rejected under 35 U.S.C. 103(a) as being unpatentable over US 5925556, US 6066492, JP 9-11046755, Williams and ATCC Catalogue.

Claims are directed to a method for degrading polylactide resins wherein the polylactide resins are degraded by an actinomycete species belonging to the genus *Saccharothrix* including species *Saccharothrix flava*, *Saccharothrix coeruleofusca*, *Saccharothrix longispora*, *Saccharothrix australiensis*, *Saccharothrix mutabilis subsp. mutabilis*, *Saccharothrix aerocolonigenes*, *Saccharothrix syringae*, and other representatives of the microbial genus *Saccharothrix*. The polylactide resins are poly-L-lactic acid or poly-L/D-lactic acid.

The cited patents US 5,925,556 and US 6,066,492 teach methods for degrading polylactide resins such as poly-L-lactic acid or poly-L/D-lactic acid. The cited patents clearly teach that actinomycetes belonging to the genus of *Saccharothrix* (see table "1-5") are suitable for degrading polylactide resins (see paragraphs preceding table "1-1"). But the cited patents US 5,925,556 and US 6,066,492 are missing disclosure about particular microbial species within the microbial genus of *Saccharothrix*.

However, the ATCC catalogue is relied upon for the disclosure of a large list of known and available representatives of the microbial genus *Saccharothrix* including all presently claimed species such as, for example: *Saccharothrix flava*, *Saccharothrix coeruleofusca*, *Saccharothrix longispora*, *Saccharothrix australiensis*, *Saccharothrix mutabilis subsp. mutabilis*, *Saccharothrix aerocolonigenes*, *Saccharothrix syringae*, and others (see pages 314-315).

Thus, the ATCC catalogue demonstrates that all presently claimed species are known and available in the prior art. In addition, the ATCC catalogue is also relied upon to demonstrate that the microbial group of actinomycetes have been frequently reclassified and that the various representatives of *Saccharothrix* have been previously assigned to *Streptomyces* and/or to *Actinomadura*. The other cited documents that are JP 9-11046755 and the reference by Williams

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teach methods for degrading polylactide resins by the actinomycete belonging to *Actinomadura* (See English abstract of JP 9-11046755) and by enzymes of *Streptomyces*. (see table 1 in the reference by Williams).

Therefore, it would have been obvious to one having ordinary skill in the art at the time the claimed invention was made to practice a method for degrading polylactide resins by using various microbial species of the microbial genus of *Saccharothrix* with a reasonable expectation of success in degrading polylactide resins because it is known that the polylactide resins are degraded by actinomycetes belonging to the genus of *Saccharothrix* as taught by US 5,925,556 and US 6,066,492 and because the polylactide resins are degraded by microbial enzymes of actinomycetes (Williams D.F.) and the representatives of the genus *Saccharothrix* previously identified as *Streptomyces* and *Actinomadura* (as demonstrated by ATCC catalogue) possess the enzymes which degrade polylactide resins (US 5,925,556; US 6,066,492; JP 9-11046755; Williams D.F.) . One of skill in the art is free to select any actinomycete representatives available in the prior art including representatives of the whole genus *Saccharothrix*. Thus, it would have been obvious to one having ordinary skill in the art at the time the claimed invention was made to use any and all representatives of the genus *Saccharothrix* from the ATCC Catalogue in the method of the cited US 5,925,556; US 6,066,492, JP 9-11-046755 and/or Williams D.F. for the expected benefits in degrading polylactide resins. Thus, the claimed invention as a whole was clearly prima facie obvious, especially in the absence of evidence to the contrary.

The claimed subject matter fails to patentably distinguish over the state art as represented by the cited references. Therefore, the claims are properly rejected under 35 USC 103.

Response to Arguments

Applicant's arguments filed 12/17/2003 have been fully considered but they are not persuasive.

With regard to the secondary references {JP 9-11046755, Williams and the ATCC Catalogue} applicant appear to argue that they do not teach the single *Saccharothrix* species that degrade lactic acid polymers (response page 6). However, these references are relied upon to demonstrate the fact that actinomycetes as the whole group of microorganisms are capable of degrading lactic acid polymers and that the assignment to the specific taxonomic genus and/or to specific taxonomic species within the group of actinomycetes has been frequently reevaluated. Thus, it is obvious that the actinomycetes as the whole group of microorganisms are suitable for degrading lactic acid polymers as taught by US 5,925,556 and US 6,066,492 for several actinomycete genera including the genus of *Saccharothrix*.

Applicant's argument that the fact that one species display activity of interest does not indicate that the other species possess that activity is not found persuasive as applied to the present invention. It is not persuasive because the whole genus *Saccharothrix* is said to be suitable for degrading polylactide resins as clearly disclosed by US 5,925,556 and US 6,066,492. The presently claimed list of the *Saccharothrix* species includes all known species within this *Saccharothrix* genus. Thus, if the whole genus is suitable for degrading polylactide resins, all known species of this genus are reasonably expected to be suitable for the same or similar method of degrading polylactide resins and all known species of this genus are reasonably expected to manifest the same activity to at least some degree.

Further, applicant appears to argue that some particular strains (that are specific products), do not demonstrate polylactide resins degrading activity (response page 6, last 2 lines, Exhibit A). Yet, the claimed invention is not limited to any particular strains including the strains assigned to the claimed species. The instant specification discloses particular *Saccharothrix* strains that are capable to degrade polylactide resins (specification 7, table 2). However, it is not yet clear whether the disclosed strains are the novel strains and/or whether there would be any differences in the methods for degrading polylactide resins between the disclosed strains and the other strains available from the bacterial culture collections. Moreover, the deposit requirement issue of the strains disclosed by applicants in the specification table 2 is not yet certain on the record.

No claims are allowed.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

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however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vera Afremova whose telephone number is (571) 272-0914. The examiner can normally be reached from Monday to Friday from 9.30 am to 6.00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached at (571) 272-0926.

The fax phone number for the TC 1600 where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Vera Afremova

AU 1651

March 16, 2004



VERA AFREMOVA

PATENT EXAMINER